Kimberly-Clark Corporation K102032 SEP - 8 2010

Traditional 510(k) Notification (Bundled):
Kimberly-Clark PURPLE NITRILE-XTRA* Sterile Powder-Free Exam Gloves - 12" Pairs

Section 5 - 510(k) Summary

Preparation Date:	July 06, 2010
Applicant:	Kimberly Clark Corporation 1400 Holcomb Bridge Road Roswell, GA 30097
Contact Person:	Lester F. Padilla Tel. No.: 678-352-6766
Trade/Proprietary Name(s):	Kimberly-Clark PURPLE NITRILE-XTRA* Sterile Powder-Free Exam Gloves – 12" Pairs
Common Name(s):	Powder-Free Nitrile Patient Examination Gloves (Sterile)
Classification Name:	Patient Examination Glove (21 CFR Part 880.6250), Polymer Patient Examination Glove (Product Code LZA)

Legally Marketed Device(s) to Which Substantial Equivalence is Claimed:

1. Safeskin Sterile PURPLE NITRILE* Examination Gloves (Powder-Free) – K992062
2. Safeskin PURPLE* Powder-Free Nitrile Examination Gloves for Use with Chemotherapeutic Drugs Labeling Claim - K992162
3. Kimberly-Clark Sterling Nitrile & Nitrile Xtra Powder-Free Exam Gloves with Chemotherapy Drug Use Claim - K081089
4. Kimberly-Clark Sterile Sterling Nitrile Powder-Free Exam Glove - K081027

Device Description(s):

Kimberly-Clark PURPLE NITRILE-XTRA* Sterile Powder-Free Exam Gloves are 12-inch long, sterile, purple-colored nitrile, powder-free, ambidextrous patient examination glove that meets all of the requirements of ASTM D 6319-00a, *Standard Specification for Nitrile Examination Gloves for Medical Application.* The gloves are packaged as two gloves per sterile pouch.

Intended Use(s):

A powder-free patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

Summary of Technologies:

The technological characteristics (design, specification, performance) of the Subject Devices and the Predicate Devices are substantially equivalent.

Non-Clinical Testing:

Characteristics	Applicable FDA-Recognized Standards	Performance Results
Dimensions	ASTM D 6319-00a	Meets ASTM Requirements
Physical Properties	ASTM D 6319-00a	Meets ASTM Requirements
Freedom from pinholes	ASTM D 6319-00a ASTM D 5151-06	Meets ASTM Requirements
Powder Free (Powder Content)	ASTM D 6319-00a ASTM D 6124-06	Meets ASTM Requirements
ISO Skin Irritation Study and Sensitization ISO Cytotoxicity Study	ISO 10993, Part 10 ISO 10993, Part 5	Meets ASTM Requirements

Clinical Testing:
No Clinical testing was required to determine substantial equivalence of these devices.

Conclusion:
The results of the non-clinical testing demonstrate that the gloves meet the FDA-recognized consensus standards and are substantially equivalent to the predicate devices.

Traditional 510(k) Notification (Bundled):
Kimberly-Clark PURPLE NITRILE* Sterile Powder-Free Exam Gloves - 9.5" Pairs

Section 5 - 510(k) Summary

Preparation Date:	July 06, 2010
Applicant:	Kimberly Clark Corporation 1400 Holcomb Bridge Road Roswell, GA 30097
Contact Person:	Lester F. Padilla Tel. No.: 678-352-6766
Trade/Proprietary Name(s):	Kimberly-Clark PURPLE NITRILE* Sterile Powder-Free Exam Gloves – 9.5" Pairs
Common Name(s):	Powder-Free Nitrile Patient Examination Glove (Sterile)
Classification Name:	Patient Examination Glove (21 CFR Part 880.6250), Polymer Patient Examination Glove (Product Code LZA)

Legally Marketed Device(s) to Which Substantial Equivalence is Claimed:

1. Safeskin Sterile PURPLE NITRILE* Examination Gloves (Powder-Free) – K992062
2. Safeskin PURPLE* Powder-Free Nitrile Examination Gloves for Use with Chemotherapeutic Drugs Labeling Claim - K992162
3. Kimberly-Clark Sterling Nitrile & Nitrile Xtra Powder-Free Exam Gloves with Chemotherapy Drug Use Claim - K081089
4. Kimberly-Clark Sterile Sterling Nitrile Powder-Free Exam Glove - K081027

Device Description(s):

Kimberly-Clark PURPLE NITRILE* Sterile Powder-Free Exam Gloves are 9.5-inch long, sterile, purple-colored nitrile, powder-free, ambidextrous patient examination glove that meets all of the requirements of ASTM D 6319-00a, *Standard Specification for Nitrile Examination Gloves for Medical Application*. The gloves are packaged as two gloves per sterile pouch.

Intended Use(s):

A powder-free patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

Summary of Technologies:

The technological characteristics (design, specification, performance) of the Subject Devices and the Predicate Devices are substantially equivalent.

Non-Clinical Testing:

Characteristics	Applicable FDA-Recognized Standards	Performance Results
Dimensions	ASTM D 6319-00a	Meets ASTM Requirements
Physical Properties	ASTM D 6319-00a	Meets ASTM Requirements
Freedom from pinholes	ASTM D 6319-00a ASTM D 5151-06	Meets ASTM Requirements
Powder Free (Powder Content)	ASTM D 6319-00a ASTM D 6124-06	Meets ASTM Requirements
ISO Skin Irritation Study and Sensitization ISO Cytotoxicity Study	ISO 10993, Part 10 ISO 10993, Part 5	Meets ASTM Requirements

Clinical Testing:
No Clinical testing was required to determine substantial equivalence of these devices.

Conclusion:
The results of the non-clinical testing demonstrate that the gloves meet the FDA-recognized consensus standards and are substantially equivalent to the predicate devices.

Traditional 510(k) Notification (Bundled):
Kimberly-Clark PURPLE NITRILE* Sterile Powder-Free Exam Gloves - 9.5 Singles

Section 5 - 510(k) Summary

Preparation Date:	July 06, 2010
Applicant:	Kimberly Clark Corporation 1400 Holcomb Bridge Road Roswell, GA 30097
Contact Person:	Lester F. Padilla Tel. No.: 678-352-6766
Trade/Proprietary Name(s):	Kimberly-Clark PURPLE NITRILE* Sterile Powder-Free Exam Gloves – 9.5" Singles
Common Name(s):	Powder-Free Nitrile Patient Examination Glove (Sterile)
Classification Name:	Patient Examination Glove (21 CFR Part 880.6250), Polymer Patient Examination Glove (Product Code LZA)

Legally Marketed Device(s) to Which Substantial Equivalence is Claimed:

1. Safeskin Sterile PURPLE NITRILE* Examination Gloves (Powder-Free) – K992062
2. Safeskin PURPLE* Powder-Free Nitrile Examination Gloves for Use with Chemotherapeutic Drugs Labeling Claim - K992162
3. Kimberly-Clark Sterling Nitrile & Nitrile Xtra Powder-Free Exam Gloves with Chemotherapy Drug Use Claim - K081089
4. Kimberly-Clark Sterile Sterling Nitrile Powder-Free Exam Glove - K081027

Device Description(s):

Kimberly-Clark PURPLE NITRILE* Sterile Powder-Free Exam Gloves are 9.5-inch long, sterile, purple-colored nitrile, powder-free, ambidextrous patient examination glove that meets all of the requirements of ASTM D 6319-00a, *Standard Specification for Nitrile Examination Gloves for Medical Application*. The gloves are packaged as one glove per sterile pouch.

Intended Use(s):

A powder-free patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

Summary of Technologies:

The technological characteristics (design, specification, performance) of the Subject Devices and the Predicate Devices are substantially equivalent.

Non-Clinical Testing:

Characteristics	Applicable FDA-Recognized Standards	Performance Results
Dimensions	ASTM D 6319-00a	Meets ASTM Requirements
Physical Properties	ASTM D 6319-00a	Meets ASTM Requirements
Freedom from pinholes	ASTM D 6319-00a ASTM D 5151-06	Meets ASTM Requirements
Powder Free (Powder Content)	ASTM D 6319-00a ASTM D 6124-06	Meets ASTM Requirements
ISO Skin Irritation Study and Sensitization ISO Cytotoxicity Study	ISO 10993, Part 10 ISO 10993, Part 5	Meets ASTM Requirements

Clinical Testing:
No Clinical testing was required to determine substantial equivalence of these devices.

Conclusion:
The results of the non-clinical testing demonstrate that the gloves meet the FDA-recognized consensus standards and are substantially equivalent to the predicate devices.

Kimberly-Clark Corporation

K102032
Traditional 510(k) Notification (Bundled):
Kimberly-Clark PURPLE NITRILE-XTRA* Sterile Powder-Free Exam Gloves (Chemotherapy Glove) – 12" Pairs

Section 5 - 510(k) Summary

Preparation Date:	August 18, 2010
Applicant:	Kimberly Clark Corporation 1400 Holcomb Bridge Road Roswell, GA 30097
Contact Person:	Lester F. Padilla Tel. No.: 678-352-6766
Trade/Proprietary Name(s):	Kimberly-Clark PURPLE NITRILE-XTRA* Sterile Powder-Free Exam Gloves (Chemotherapy Glove) – 12" Pairs
Common Name(s):	Powder-Free Nitrile Patient Examination Chemotherapy Use Glove (Sterile)
Classification Name:	Patient Examination Glove (21 CFR Part 880.6250), Patient Examination Glove, Specialty (Product Code LZC)

Legally Marketed Device(s) to Which Substantial Equivalence is Claimed:

1. Safeskin Sterile PURPLE NITRILE* Examination Gloves (Powder-Free) – K992062
2. Safeskin PURPLE* Powder-Free Nitrile Examination Gloves for Use with Chemotherapeutic Drugs Labeling Claim - K992162
3. Kimberly-Clark Sterling Nitrile & Nitrile Xtra Powder-Free Exam Gloves with Chemotherapy Drug Use Claim - K081089
4. Kimberly-Clark Sterile Sterling Nitrile Powder-Free Exam Glove - K081027

Device Description(s):

Kimberly-Clark PURPLE NITRILE-XTRA* Sterile Powder-Free Exam Gloves (Chemotherapy Glove) are 12-inch long, sterile, purple-colored nitrile, powder-free, ambidextrous patient examination glove that meets all of the requirements of ASTM D 6319-00a, *Standard Specification for Nitrile Examination Gloves for Medical Application.* In addition these gloves were tested for use with the drugs listed in the Intended Use(s) section below, per ASTM D6978-05 *"Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs."* The gloves are packaged as two gloves per sterile pouch.

Intended Use(s):

A powder-free patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

In addition, these chemotherapy gloves were tested for use with the following drug concentrations per ASTM D6978-05:

The following drugs had NO breakthrough detected up to 240 minutes:

Bleomycin sulfate (15.0mg/ml)	Idarubicin (1.0mg/ml)
Busulfan (6.0mg/ml)	Ifosfamide (50mg/ml)
Carboplatin (10.0mg/ml)	Irinotecan (20.0mg/ml)
Cisplatin (1 mg/ml)	Mechlorethamine HCl (1.0mg/ml)
Cyclophosphamide (20 mg/ml)	Melphalan (5.0mg/ml)
Cytarabine HCl (100.0mg/ml)	Methotrexate (25.0mg/ml)
Dacarbazine (10 mg/ml)	Mitomycin (0.5mg/ml)
Daunorubicin Hcl (5.0mg/ml)	Mitoxantrone (2 mg/ml)
Docetaxel (10.0mg/ml)	Paclitaxel (Taxol) (6 mg/ml)
Doxorubicin HCl (Adriamycin) (2 mg/ml)	Paraplatin (10.0mg/ml)
Ellence (Epirubicin) (2.0mg/ml)	Rituximab (10.0mg/ml)
Etoposide (20 mg/ml)	ThioTEPA (10.0mg/ml)
Fludarabine (25.0mg/ml)	Trisenox (0.1mg/ml)
Fluorouracil (adrucil) (50 mg/ml)	Vincristine Sulfate (1 mg/ml)
Gemcitabine (38.0mg/ml)	

Please note that the following drug has extremely low permeation times of less than 60 minutes:
Carmustine (3.3 mg/ml) 48.6 minutes

Summary of Technologies:

The technological characteristics (design, specification, performance) of the Subject Devices and the Predicate Devices are substantially equivalent.

Non-Clinical Testing:

Characteristics	Applicable FDA-Recognized Standards	Performance Results
Dimensions	ASTM D 6319-00a	Meets ASTM Requirements
Physical Properties	ASTM D 6319-00a	Meets ASTM Requirements
Freedom from pinholes	ASTM D 6319-00a ASTM D 5151-06	Meets ASTM Requirements
Powder Free (Powder Content)	ASTM D 6319-00a ASTM D 6124-06	Meets ASTM Requirements
ISO Skin Irritation Study and Sensitization ISO Cytotoxicity Study	ISO 10993, Part 10 ISO 10993, Part 5	Meets ASTM Requirements
Resistance to Permeation	ASTM D 6978-05 and/or ASTM F 739-07	Meets ASTM Requirements See Intended Use Section

Clinical Testing:
No Clinical testing was required to determine substantial equivalence of these devices.

Conclusion:
The results of the non-clinical testing demonstrate that the gloves meet the FDA-recognized consensus standards and are substantially equivalent to the predicate devices.

Kimberly-Clark Corporation

K102032
Traditional 510(k) Notification (Bundled):
Kimberly-Clark PURPLE NITRILE* Sterile Powder-Free Exam Gloves (Chemotherapy Glove) – 9.5" Pairs

Section 5 - 510(k) Summary

Preparation Date:	August 18, 2010
Applicant:	Kimberly Clark Corporation 1400 Holcomb Bridge Road Roswell, GA 30097
Contact Person:	Lester F. Padilla Tel. No.: 678-352-6766
Trade/Proprietary Name(s):	Kimberly-Clark PURPLE NITRILE* Sterile Powder-Free Exam Gloves (Chemotherapy Glove) – 9.5" Pairs
Common Name(s):	Powder-Free Nitrile Patient Examination Chemotherapy Use Glove (Sterile)
Classification Name:	Patient Examination Glove (21 CFR Part 880.6250), Patient Examination Glove, Specialty (Product Code LZC)

Legally Marketed Device(s) to Which Substantial Equivalence is Claimed:

1. Safeskin Sterile PURPLE NITRILE* Examination Gloves (Powder-Free) – K992062
2. Safeskin PURPLE* Powder-Free Nitrile Examination Gloves for Use with Chemotherapeutic Drugs Labeling Claim - K992162
3. Kimberly-Clark Sterling Nitrile & Nitrile Xtra Powder-Free Exam Gloves with Chemotherapy Drug Use Claim - K081089
4. Kimberly-Clark Sterile Sterling Nitrile Powder-Free Exam Glove - K081027

Device Description(s):

Kimberly-Clark PURPLE NITRILE* Sterile Powder-Free Exam Gloves (Chemotherapy Glove) are 9.5-inch long, sterile, purple-colored nitrile, powder-free, ambidextrous patient examination glove that meets all of the requirements of ASTM D 6319-00a, *Standard Specification for Nitrile Examination Gloves for Medical Application*. In addition these gloves were tested for use with the drugs listed in the Intended Use(s) section below, per ASTM D6978-05 *"Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs."* The gloves are packaged as two gloves per sterile pouch.

K102032
Traditional 510(k) Notification (Bundled):
Kimberly-Clark PURPLE NITRILE* Sterile Powder-Free Exam Gloves
(Chemotherapy Glove) – 9.5" Pairs

Intended Use(s):

A powder-free patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

In addition, these chemotherapy gloves were tested for use with the following drug concentrations per ASTM D6978-05:

The following drugs had NO breakthrough detected up to 240 minutes:

Bleomycin sulfate (15.0mg/ml)	Idarubicin (1.0mg/ml)
Busulfan (6.0mg/ml)	Ifosfamide (50mg/ml)
Carboplatin (10.0mg/ml)	Irinotecan (20.0mg/ml)
Cisplatin (1 mg/ml)	Mechlorethamine HCl (1.0mg/ml)
Cyclophosphamide (20 mg/ml)	Melphalan (5.0mg/ml)
Cytarabine HCl (100.0mg/ml)	Methotrexate (25.0mg/ml)
Dacarbazine (10 mg/ml)	Mitomycin (0.5mg/ml)
Daunorubicin Hcl (5.0mg/ml)	Mitoxantrone (2 mg/ml)
Docetaxel (10.0mg/ml)	Paclitaxel (Taxol) (6 mg/ml)
Doxorubicin HCl (Adriamycin) (2 mg/ml)	Paraplatin (10.0mg/ml)
Ellence (Epirubicin) (2.0mg/ml)	Rituximab (10.0mg/ml)
Etoposide (20 mg/ml)	ThioTEPA (10.0mg/ml)
Fludarabine (25.0mg/ml)	Trisenox (0.1mg/ml)
Fluorouracil (adrucil) (50 mg/ml)	Vincristine Sulfate (1 mg/ml)
Gemcitabine (38.0mg/ml)	

Please note that the following drug has extremely low permeation times of less than 60 minutes:
Carmustine (3.3 mg/ml) 48.6 minutes

Summary of Technologies:

The technological characteristics (design, specification, performance) of the Subject Devices and the Predicate Devices are substantially equivalent.

K102032
Traditional 510(k) Notification (Bundled):
Kimberly-Clark PURPLE NITRILE* Sterile Powder-Free Exam Gloves
(Chemotherapy Glove) – 9.5" Pairs

Non-Clinical Testing:

Characteristics	Applicable FDA-Recognized Standards	Performance Results
Dimensions	ASTM D 6319-00a	Meets ASTM Requirements
Physical Properties	ASTM D 6319-00a	Meets ASTM Requirements
Freedom from pinholes	ASTM D 6319-00a ASTM D 5151-06	Meets ASTM Requirements
Powder Free (Powder Content)	ASTM D 6319-00a ASTM D 6124-06	Meets ASTM Requirements
ISO Skin Irritation Study and Sensitization ISO Cytotoxicity Study	ISO 10993, Part 10 ISO 10993, Part 5	Meets ASTM Requirements
Resistance to Permeation	ASTM D 6978-05 and/or ASTM F 739-07	Meets ASTM Requirements See Intended Use Section

Clinical Testing:
No Clinical testing was required to determine substantial equivalence of these devices.

Conclusion:
The results of the non-clinical testing demonstrate that the gloves meet the FDA-recognized consensus standards and are substantially equivalent to the predicate devices.

Kimberly-Clark Corporation

K102032
Traditional 510(k) Notification (Bundled):
Kimberly-Clark PURPLE NITRILE* Sterile Powder-Free Exam Gloves (Chemotherapy Glove) – 9.5" Singles

Section 5 - 510(k) Summary

Preparation Date:	August 18, 2010
Applicant:	Kimberly Clark Corporation 1400 Holcomb Bridge Road Roswell, GA 30097
Contact Person:	Lester F. Padilla Tel. No.: 678-352-6766
Trade/Proprietary Name(s):	Kimberly-Clark PURPLE NITRILE* Sterile Powder-Free Exam Gloves (Chemotherapy Glove) – 9.5" Single
Common Name(s):	Powder-Free Nitrile Patient Examination Chemotherapy Use Glove (Sterile)
Classification Name:	Patient Examination Glove (21 CFR Part 880.6250), Patient Examination Glove, Specialty (Product Code LZC)

Legally Marketed Device(s) to Which Substantial Equivalence is Claimed:

1. Safeskin Sterile PURPLE NITRILE* Examination Gloves (Powder-Free) – K992062
2. Safeskin PURPLE* Powder-Free Nitrile Examination Gloves for Use with Chemotherapeutic Drugs Labeling Claim - K992162
3. Kimberly-Clark Sterling Nitrile & Nitrile Xtra Powder-Free Exam Gloves with Chemotherapy Drug Use Claim - K081089
4. Kimberly-Clark Sterile Sterling Nitrile Powder-Free Exam Glove - K081027

Device Description(s):

Kimberly-Clark PURPLE NITRILE* Sterile Powder-Free Exam Gloves (Chemotherapy Glove) are 9.5-inch long, sterile, purple-colored nitrile, powder-free, ambidextrous patient examination glove that meets all of the requirements of ASTM D 6319-00a, *Standard Specification for Nitrile Examination Gloves for Medical Application.* In addition these gloves were tested for use with the drugs listed in the Intended Use(s) section below, per ASTM D6978-05 *"Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs."* The gloves are packaged as one glove per sterile pouch.

K102032
Traditional 510(k) Notification (Bundled):
Kimberly-Clark PURPLE NITRILE* Sterile Powder-Free Exam Gloves
(Chemotherapy Glove) – 9.5" Singles

Intended Use(s):

A powder-free patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

In addition, these chemotherapy gloves were tested for use with the following drug concentrations per ASTM D6978-05:

The following drugs had NO breakthrough detected up to 240 minutes:

Bleomycin sulfate (15.0mg/ml)	Idarubicin (1.0mg/ml)
Busulfan (6.0mg/ml)	Ifosfamide (50mg/ml)
Carboplatin (10.0mg/ml)	Irinotecan (20.0mg/ml)
Cisplatin (1 mg/ml)	Mechlorethamine HCl (1.0mg/ml)
Cyclophosphamide (20 mg/ml)	Melphalan (5.0mg/ml)
Cytarabine HCl (100.0mg/ml)	Methotrexate (25.0mg/ml)
Dacarbazine (10 mg/ml)	Mitomycin (0.5mg/ml)
Daunorubicin Hcl (5.0mg/ml)	Mitoxantrone (2 mg/ml)
Docetaxel (10.0mg/ml)	Paclitaxel (Taxol) (6 mg/ml)
Doxorubicin HCl (Adriamycin) (2 mg/ml)	Paraplatin (10.0mg/ml)
Ellence (Epirubicin) (2.0mg/ml)	Rituximab (10.0mg/ml)
Etoposide (20 mg/ml)	ThioTEPA (10.0mg/ml)
Fludarabine (25.0mg/ml)	Trisenox (0.1mg/ml)
Fluorouracil (adrucil) (50 mg/ml)	Vincristine Sulfate (1 mg/ml)
Gemcitabine (38.0mg/ml)	

Please note that the following drug has extremely low permeation times of less than 60 minutes:
Carmustine (3.3 mg/ml) 48.6 minutes

Summary of Technologies:

The technological characteristics (design, specification, performance) of the Subject Devices and the Predicate Devices are substantially equivalent.

K102032
Traditional 510(k) Notification (Bundled):
Kimberly-Clark PURPLE NITRILE* Sterile Powder-Free Exam Gloves
(Chemotherapy Glove) – 9.5" Singles

Non-Clinical Testing:

Characteristics	Applicable FDA-Recognized Standards	Performance Results
Dimensions	ASTM D 6319-00a	Meets ASTM Requirements
Physical Properties	ASTM D 6319-00a	Meets ASTM Requirements
Freedom from pinholes	ASTM D 6319-00a ASTM D 5151-06	Meets ASTM Requirements
Powder Free (Powder Content)	ASTM D 6319-00a ASTM D 6124-06	Meets ASTM Requirements
ISO Skin Irritation Study and Sensitization ISO Cytotoxicity Study	ISO 10993, Part 10 ISO 10993, Part 5	Meets ASTM Requirements
Resistance to Permeation	ASTM D 6978-05 and/or ASTM F 739-07	Meets ASTM Requirements See Intended Use Section

Clinical Testing:
No Clinical testing was required to determine substantial equivalence of these devices.

Conclusion:
The results of the non-clinical testing demonstrate that the gloves meet the FDA-recognized consensus standards and are substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Kimberly-Clark Corporation
C/O Mr. Ned Divine
Responsible Third Party Official
Underwriters Laboratories, Incorporated
333 Pfingsten Road
Northbrook, Illinois 60062

SEP 0 8 2010

Re: K102032
Trade/Device Name: Kimberly-Clark Purple NITRILE-XTRA *Sterile Powder-Free Examination Glove with Tested For Use with Chemotherapy Drug Labeling Claim (12"Pairs)
Labeling Claim (12"Pairs)
Kimberly-Clark Purple NITRILE Sterile Powder-Free Examination Glove with Tested For Use with Chemotherapy Labeling Claim (9.5"Pairs)
Kimberly-Clark Purple NITRILE Sterile Powder Free Examination Glove with Tested For Use with Chemotherapy Drug Labeling Claim (9.5"Single)
Kimberly-Clark Purple NITRILE-XTRA * Sterile Powder-Free Examination Glove (12"Pairs)
Kimberly-Clark Purple NITRILE * Sterile Powder-Free Examination Glove (9.5"Pairs)
Kimberly-Clark Purple NITRILE* Sterile Powder-Free Examination Glove (9.5"Single)
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LZA, LZC
Dated: August 18, 2010
Received: August 20, 2010

Dear Mr. Devine:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act.

The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Kimberly-Clark Corporation

Indications for Use

510(k) Number (if known): K102032

Device Name(s):
Kimberly-Clark PURPLE NITRILE-XTRA* Sterile Powder-Free Exam Glove (Chemotherapy Glove) – 12" Pairs

Indications for Use:
A powder-free patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

In addition, these chemotherapy gloves were tested for use with the following drug concentrations per ASTM D6978-05:

The following drugs had NO breakthrough detected up to 240 minutes:

Bleomycin sulfate (15.0mg/ml)	Idarubicin (1.0mg/ml)
Busulfan (6.0mg/ml)	Ifosfamide (50mg/ml)
Carboplatin (10.0mg/ml)	Irinotecan (20.0mg/ml)
Cisplatin (1 mg/ml)	Mechlorethamine HCl (1.0mg/ml)
Cyclophosphamide (20 mg/ml)	Melphalan (5.0mg/ml)
Cytarabine HCl (100.0mg/ml)	Methotrexate (25.0mg/ml)
Dacarbazine (10 mg/ml)	Mitomycin (0.5mg/ml)
Daunorubicin Hcl (5.0mg/ml)	Mitoxantrone (2 mg/ml)
Docetaxel (10.0mg/ml)	Paclitaxel (Taxol) (6 mg/ml)
Doxorubicin HCl (Adriamycin) (2 mg/ml)	Paraplatin (10.0mg/ml)
Ellence (Epirubicin) (2.0mg/ml)	Rituximab (10.0mg/ml)
Etoposide (20 mg/ml)	ThioTEPA (10.0mg/ml)
Fludarabine (25.0mg/ml)	Trisenox (0.1mg/ml)
Fluorouracil (adrucil) (50 mg/ml)	Vincristine Sulfate (1 mg/ml)
Gemcitabine (38.0mg/ml)	

Please note that the following drug has extremely low permeation times of less than 60 minutes: Carmustine (3.3 mg/ml) 48.6 minutes

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K102032

Kimberly-Clark Corporation

Indications for Use (cont'd)

510(k) Number (if known): K102032

Device Name(s):
Kimberly-Clark PURPLE NITRILE-XTRA* Sterile Powder-Free Exam Glove (Chemotherapy Glove) – 12" Sterile Pairs

Prescription Use _____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use ___X___ (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K102032

Kimberly-Clark Corporation

Indications for Use

510(k) Number (if known): K102032

Device Name(s):
Kimberly-Clark PURPLE NITRILE* Sterile Powder-Free Exam Glove (Chemotherapy Glove) – 9.5" Pairs

Indications for Use:
A powder-free patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

In addition, these chemotherapy gloves were tested for use with the following drug concentrations per ASTM D6978-05:

The following drugs had NO breakthrough detected up to 240 minutes:

Bleomycin sulfate (15.0mg/ml)	Idarubicin (1.0mg/ml)
Busulfan (6.0mg/ml)	Ifosfamide (50mg/ml)
Carboplatin (10.0mg/ml)	Irinotecan (20.0mg/ml)
Cisplatin (1 mg/ml)	Mechlorethamine HCl (1.0mg/ml)
Cyclophosphamide (20 mg/ml)	Melphalan (5.0mg/ml)
Cytarabine HCl (100.0mg/ml)	Methotrexate (25.0mg/ml)
Dacarbazine (10 mg/ml)	Mitomycin (0.5mg/ml)
Daunorubicin Hcl (5.0mg/ml)	Mitoxantrone (2 mg/ml)
Docetaxel (10.0mg/ml)	Paclitaxel (Taxol) (6 mg/ml)
Doxorubicin HCl (Adriamycin) (2 mg/ml)	Paraplatin (10.0mg/ml)
Ellence (Epirubicin) (2.0mg/ml)	Rituximab (10.0mg/ml)
Etoposide (20 mg/ml)	ThioTEPA (10.0mg/ml)
Fludarabine (25.0mg/ml)	Trisenox (0.1mg/ml)
Fluorouracil (adrucil) (50 mg/ml)	Vincristine Sulfate (1 mg/ml)
Gemcitabine (38.0mg/ml)	

Please note that the following drug has extremely low permeation times of less than 60 minutes: Carmustine (3.3 mg/ml) 48.6 minutes

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K102032

Kimberly-Clark Corporation

Indications for Use (cont'd)

510(k) Number (if known): K102032

Device Name(s):
Kimberly-Clark PURPLE NITRILE* Sterile Powder-Free Exam Glove (Chemotherapy Glove) – 9.5" Sterile Pairs

Prescription Use _____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use ___X___ (21 CFR 801 Subpart C)

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(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K 102032

Kimberly-Clark Corporation

Indications for Use

510(k) Number (if known): K102032

Device Name(s):
Kimberly-Clark PURPLE NITRILE* Sterile Powder-Free Exam Glove (Chemotherapy Glove) – 9.5" Singles

Indications for Use:
A powder-free patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

In addition, these chemotherapy gloves were tested for use with the following drug concentrations per ASTM D6978-05:

The following drugs had NO breakthrough detected up to 240 minutes:

Bleomycin sulfate (15.0mg/ml)	Idarubicin (1.0mg/ml)
Busulfan (6.0mg/ml)	Ifosfamide (50mg/ml)
Carboplatin (10.0mg/ml)	Irinotecan (20.0mg/ml)
Cisplatin (1 mg/ml)	Mechlorethamine HCl (1.0mg/ml)
Cyclophosphamide (20 mg/ml)	Melphalan (5.0mg/ml)
Cytarabine HCl (100.0mg/ml)	Methotrexate (25.0mg/ml)
Dacarbazine (10 mg/ml)	Mitomycin (0.5mg/ml)
Daunorubicin Hcl (5.0mg/ml)	Mitoxantrone (2 mg/ml)
Docetaxel (10.0mg/ml)	Paclitaxel (Taxol) (6 mg/ml)
Doxorubicin HCl (Adriamycin) (2 mg/ml)	Paraplatin (10.0mg/ml)
Ellence (Epirubicin) (2.0mg/ml)	Rituximab (10.0mg/ml)
Etoposide (20 mg/ml)	ThioTEPA (10.0mg/ml)
Fludarabine (25.0mg/ml)	Trisenox (0.1mg/ml)
Fluorouracil (adrucil) (50 mg/ml)	Vincristine Sulfate (1 mg/ml)
Gemcitabine (38.0mg/ml)	

Please note that the following drug has extremely low permeation times of less than 60 minutes: Carmustine (3.3 mg/ml) 48.6 minutes

Elizabeth P. Lamm-Weisel

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K102032

Kimberly-Clark Corporation

Indications for Use (cont'd)

510(k) Number (if known): K102032

Device Name(s):
Kimberly-Clark PURPLE NITRILE* Sterile Powder-Free Exam Glove (Chemotherapy Glove) – 9.5" Sterile Single

Prescription Use _____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use ___X___ (21 CFR 801 Subpart C)

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Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K102032

Kimberly-Clark Corporation

Indications for Use

510(k) Number (if known): K102032

Device Name(s):
Kimberly-Clark PURPLE NITRILE-XTRA* Sterile Powder-Free Exam Glove
(12" Pairs)

Indications for Use:
A powder-free patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

Prescription Use _____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use ___X___ (21 CFR 801 Subpart C)

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Infection Control, Dental Devices

510(k) Number: K102032

Kimberly-Clark Corporation

Indications for Use

510(k) Number (if known): K102032

Device Name(s):
Kimberly-Clark PURPLE NITRILE* Sterile Powder-Free Exam Glove
(9.5" Pairs)

Indications for Use:
A powder-free patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___X___ (21 CFR 801 Subpart C)

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Elizabeth P. Lamuie-Webb
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Infection Control, Dental Devices

510(k) Number: K102032

Kimberly-Clark Corporation

Indications for Use

510(k) Number (if known): K102032

Device Name(s):
Kimberly-Clark PURPLE NITRILE* Sterile Powder-Free Exam Glove
(9.5" Singles)

Indications for Use:
A powder-free patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

Prescription Use _____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use ___X___ (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth P. Claus-Wilks

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510(k) Number: K102032